

AN

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
11 July 2002 (11.07.2002)

PCT

(10) International Publication Number
WO 02/053216 A2(51) International Patent Classification⁷: A61M 15/00SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN,
YU, ZA, ZW.

(21) International Application Number: PCT/IN02/00004

(22) International Filing Date: 7 January 2002 (07.01.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
22/MUM/2001 8 January 2001 (08.01.2001) IN(71) Applicant (for all designated States except US): CIPLA
LIMITED [IN/IN]; 289 Bellasis Road, Mumbai central,
Mumbai 400 008, Maharashtra (IN).

(72) Inventors; and

(75) Inventors/Applicants (for US only): RAO, Xerxes
[IN/IN]; Flat n°802, Moraba Mansion, Plot n°405, Linking
Road, Khar (W), Mumbai-400 052, Maharashtra (IN).
LULLA, Amar [IN/IN]; 289, Bellasis Road, Mumbai
Central, Mumbai 400 008, Maharashtra (IN).(74) Agents: BOAZ, Rani et al.; Krishna & Saurastri, 74/F,
Venus, Worli Sea Face, Mumbai 400 018, Maharashtra
(IN).(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR,
GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,
NE, SN, TD, TG).

Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted
a patent (Rule 4.17(ii)) for the following designations AE,
AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH,
CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG,
KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK,
MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD,
SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN,
YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ,
SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ,
BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE,
CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL,
PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG)
— of inventorship (Rule 4.17(iv)) for US only

Published:

— without international search report and to be republished
upon receipt of that reportFor two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: AN IMPROVED DEVICE FOR METERED ADMINISTRATION OF MEDICAMENT BY INHALATION

(57) Abstract: An improved device for metered administration of medicament by inhalation orally comprises of a container for receiving a circular cartridge of medicament. The cartridge has a plurality of cavities along its circumference to hold a predetermined quantity of medicament. Each cavity is sealed by a pierceable sealing means. A piercing member pierces the said sealing means and thereby penetrates into the cavity. The piercing member has a hollow cylindrical part in fluid communication with an inhalation nozzle. The container has a view window at a location below the nozzle to enable the user to ascertain the evacuation of medicament from the cavity pierced for use.

WO 02/053216 A2

TITLE

An Improved device for metered administration of medicament by inhalation.

FIELD OF INVENTION

5. This invention relates to an improved device for administering orally metered dose of medicinal composition by inhalation.

For patients suffering from asthma or similar recurring type of diseases, administration of medicinal preparations by inhalation orally is found to be more effective than administration of medicines by intravenous or intra-

10. muscular administrations. The patients suffering from asthma or similar diseases are advised self-administration of medicinal preparations by inhalation any time throughout the day when they get breathing inconvenience. Therefore, various devices for self-administration of metered dose of medicinal compositions by inhalation are already in

15. existence, which can be carried by the patients conveniently.

PRIOR ART

In a measure to explain one of the prior art applications, reference is hereby made to the German publication DE 19704849A describing one such inhaler device using a tubular piercing member to pierce a cartridge of medicament.

20. The tubular piercing member has a conical piercing tip with a plurality of holes for entry of the medicament. However this device suffers from the following drawbacks :

- (i). facility to judge the evacuation of medicament from cavity, upon inhalation, by user;

and

(ii). lack of sufficient fluid flow technology to ensure efficient delivery of medicament upon inhalation.

It is, therefore, the foremost objective of the present invention to obviate the above drawbacks in the known such inhaler device containing medicament cartridge pierced open by a tubular piercing member. This invention provides an inhaler device containing cartridge loaded with multiple doses of metered medicinal composition, and facility for the user to visualize the evacuation of the medicament from cavity upon inhalation. The device also adds to its part, a simple and economical construction for making it available to a common man at an affordable price.

With the above object in mind, this invention provides an inhaler device containing cartridge loaded with multiple doses of metered medicinal composition, comprising of a container formed of a circular lower chamber, an upper chamber in the form of a lid and a cartridge having multiple cavities with opening ends facing towards the lid. The lid has a tubular piercing member which is in fluid communication with a nozzle. The nozzle is adapted for inhalation by mouth. The container has a view window below the nozzle, to enable the user to ascertain the evacuation of medicament from the cavity upon inhalation. The tubular piercing member and a lever exposed on the top end of the lid and configured to operate the piercing member are connected to a common fulcrum. The piercing member has a vertical baffle oriented diametrical to its hollow interior. In operative configuration, the piercing member remains inserted into the cavity loaded with medicinal composition, and the free end of the lever remains lifted-up.

A knob with individual openings at its side walls, is welded to the upper portion of the tubular piercing member. The knob is pressed down by finger, to make the piercing member penetrate into the cavity of medicament.

5. The container has an opening on sidewall for rotating the cartridge in clockwise rotation. The cavities in the cartridge are divided by projections extending radially. Every time at least one projection penetrates through the opening on the sidewall and remains exposed to rotate the cartridge in clockwise rotation. A ratchet mechanism comprising of zig-zag projections
10. is provided in the cartridge. One slope of every zig-zag projection is configured as a curve, and the other slope is in straight line. A stopper member is positioned facing the slope in straight line, to prevent anticlockwise rotation of the cartridge. However, the curved configuration of the adjacent projection allows clockwise rotation of the cartridge. The
15. stopper member is located in position such that radial projection remains exposed at the middle of the opening on the sidewall, and two cavities adjacent to the exposed projection become visible. The cartridge is made of transparent material. Visibility through the container, facilitates knowing whether at least one cavity is left with for subsequent administration, or all
20. are exhausted.

DESCRIPTION OF THE INVENTION

The invention will now be described with reference to the accompanying illustrative drawings, which are in no way intended to restrict the scope of the invention, and are only for the sake of clear understanding of the

25. invention.

Figure 1 is a top perspective view of assembly of the inhaler device containing cartridge loaded with multiple doses of metered medicinal composition, according to the invention.

Figure 2 is a perspective view of the inhaler device, the dust cap being
5 separated from the mouth piece.

Figure 3 is the top plan of the upper chamber, i.e. lid of the inhaler device in Figures 1 and 2, the assembly of mouth adapter and dust cap being separated from the outlet nozzle.

Figure 4 is a cross-sectional view of the inhaler device shown in Figures 1
10 and 2, the section being taken along the line 'A-A' in Figure 2.

Figure 5 is a top plan of the lower chamber the stopper member, female interlocking constituent, opening on the sidewall, and hinge loop.

Figure 6 is bottom plan of the upper chamber, i.e. lid illustrating the male interlocking member, outlet nozzle, opening on the side walls, and hinge
15 pins.

Figure 7 is a blown-up view of the piercing member, illustrating the piercing point, openings on the piercing point to establish connection with the outlet nozzle, baffle, connector for connecting to the lever, and press button.

Figure 8 is the top plan of the cartridge having multiple circumferential
20 cavities, filled with doses of medicinal composition and sealed with a pierceable blister.

Figure 9 is bottom plan of the cartridge illustrating multiple radial cavities, a projection between every pair of cavities, and zig-zag inner end of cartridge.

Referring to the illustrative figures 1 and 2, container 101 is formed of a circular lower chamber 102, an upper chamber 103 in the form of a lid, and a cartridge 104 having multiple cavities 105. Open ends 106 of the cavities 105 are facing towards the lid 103. 107 is a tubular piercing member which communicates with an outlet nozzle 108. A view window 118 is provided at a location, below the nozzle 108, to judge the evacuation of the medicament from the cavity, upon inhalation. The tubular piercing member 107 is shown in detail in Figure 7. The piercing member is a hollow cylindrical part with a press button portion 704 at the top, an axial air suction hole 701 and a conical piercing tip 702 at the bottom. Multiple holes 706 are provided at the taper portion of the conical piercing tip 702 for entry of the medicament for delivery. The axial air suction hole 701 communicates with the inhalation nozzle 108, to lead air and medicament mixture upon inhalation by the user. The press button portion 704 is provided to apply necessary pressure with a finger, for penetration of the piercing member 107 into the cavity filled with medicament. A knob 703 with openings 707 at three of its side walls 709 is ultrasonically welded to the press button portion 704. A vertical baffle 708 is oriented diametrical to the axial air suction hole 701 of the tubular piercing member 107. Upon inhalation by the user through the nozzle 108, the outer air rushes through the openings 707 of the knob 703, into the axial air suction hole 701 of the tubular piercing member 107. The incoming air stream flowing towards the medicament cartridge and on one side of the baffle 708 lifts up sufficient quantity of the medicament from the cartridge, before delivery through the nozzle 108. To prevent dust accumulation, the mouth adapter 109 is provided with a dust cap 128. In the closed state of the mouth adaptor 109 by the dust cap 128, the knob

703 is restricted from being pressed down for piercing the cavity of medicament.

Referring to figures 3 and 4, the outlet of nozzle 108 is provided with a mouth adapter 109 for inhalation by mouth. The piercing member 107 and
5 a lever 110 exposed on the top end of the lid are connected to a common fulcrum 111, through a connector 121. Lever 110 operates the piercing member 107. In operative configuration of the inhaler, pressure is applied on the knob 703 by finger so that the piercing member 107 enters the cavity by piercing the sealing means on an open end of the cavity loaded with
10 medicinal composition, and the free end of the lever 110 remains lifted-up as can be seen in Figure 4. The free end of the lever is pressed down by finger to release the piercing member from the piercing position.

Referring to figures 5 and 6, the container 101 has an opening 112 through sidewalls of the lower chamber 102 and upper chamber 103. An index hole
15 131 is provided in the bottom surface of the lower chamber 102 of the container 101. An indexing disc 130 with multiple color segments 132 at the periphery on one surface, is mounted at the central location within the lower chamber 102. Each color segment represents the identity of medicine stored in the cartridge. The disc is mounted such that the color of the
20 segment when viewed from out side through the index hole, indicates to the user, the identity of the medicament stored in the cartridge.

Referring to figures 8 and 9, one of the radial projections 113 dividing cavities 105 from each other, and projecting at the lower end 114 of the cartridge is exposed through the opening 112 for manually rotating the
25 cartridge 104 to align the next filled cavity with the piercing device 107.

115 is a flexible stopper in the lower chamber 102. One end of the stopper 115 is secured with the base of the lower chamber 102, and the other free end is configured and positioned such that it remains inserted into one of the valleys 116 of the zig-zag of inner radius of the cartridge 104. The engagement of stopper 115 with one of the valleys 116 of the zig-zag of the inner radius of the cartridge 104 forms a ratchet mechanism allowing clockwise rotation of the cartridge 104, and operates as restraint for rotating it anti-clockwise. In accordance with a preferred embodiment of the invention, the stopper 115 is integrally formed at inside base of the lower chamber 102 of the container 101. Alternatively, the stopper 115 may be flexibly secured on the inside base of the lower chamber 102 of the container 101 with conventional means.

Referring back to figure 4, lower chamber 102 and upper chamber 103 of the container 101 are provided with interlocking central male member 119 and female member 120. The interlocking formed of male member 119 and female member 120 ensures proper alignment of the chambers 102 and 103 and prevents them from lateral movement. The lower chamber 102 and upper chamber 103 are joined at hinge 122, which allows lifting the upper member 103 of the container for replacement of the cartridge 104, or for any other purpose. The lower member 102 and upper member 103 of the container 101 are interlocked with the help of conventional interlocking rib and groove, or the like arrangements (not shown).

Referring to figure 10, one of the edges of every valley of the zig-zag projection adapted to face the stopper member 115 is configured as a straight line 123 and the opposing edge is configured as a curve 124. The stopper member 115 holds on the straight edge 123 and thereby prevents

anti-clockwise rotation of the cartridge 104 in the direction of arrow 125, and the curved edge 124 allows the stopper 115 to slide over and allows clockwise rotation of the cartridge in the direction of arrow 126. In order that the contents in the cavities are visible, the cartridge 104 is molded of transparent material. Visibility of two containers, facilities to know at least one container is left for subsequent administration, or all are exhausted.

We Claim :

1. An improved device for metered administration of medicament by inhalation orally comprising of a container for receiving a circular cartridge of medicament, the said cartridge having a plurality of cavities along its circumference to hold a predetermined quantity of medicament, and each cavity being sealed by a pierceable sealing means; a member for piercing the said sealing means and thereby penetrate into the cavity, the said piercing member being a hollow cylindrical part in fluid communication with an inhalation nozzle wherein the container has a view window at a location below the said nozzle to enable the user to ascertain the evacuation of medicament from the cavity pierced for use.
2. The device according to claim 1 comprises of a diametrical baffle inside the hollow cylindrical part whereby upon piercing and inhalation by user, the incoming air stream on one side of the baffle, lifts the medicament alongwith before reaching the said nozzle.
3. The device according to claim 2 comprises of a knob to close the upper part of the hollow cylindrical part wherein the knob has individual openings at three of its side walls to allow entry of outer air into the hollow interior upon inhalation by the user.
4. The device according to claim 3, further comprises of a lever connected to the said piercing member.
5. The said device according to claim 4 wherein the lever is connected to the piercing member so as to release the piercing member from the piercing position.

6. The device according to claim 5, the container further has an indexing means to identify the medicament stored in the cartridge wherein the indexing means includes an indexing disc having peripheral color segments each representing an identity of medicament, and each segment viewable distinctly from outside through an index hole at the bottom surface of lower chamber of the container, to identify the medicament stored in the cartridge.

1/4

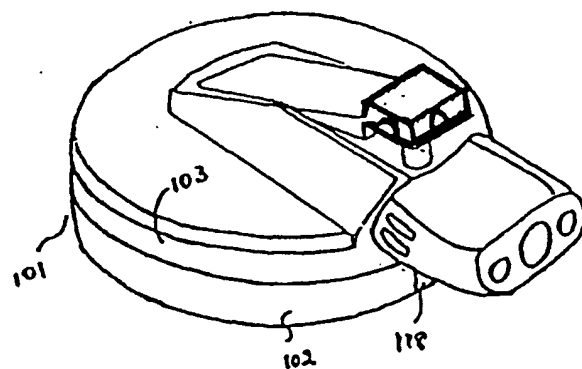


Fig. 1

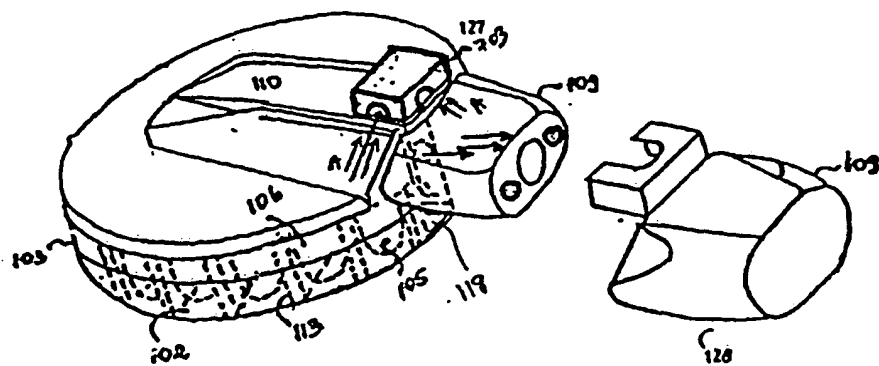


Fig. 2

2/4

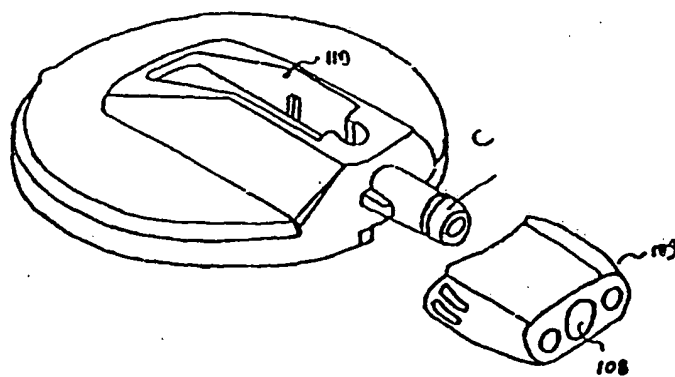


Fig . 3

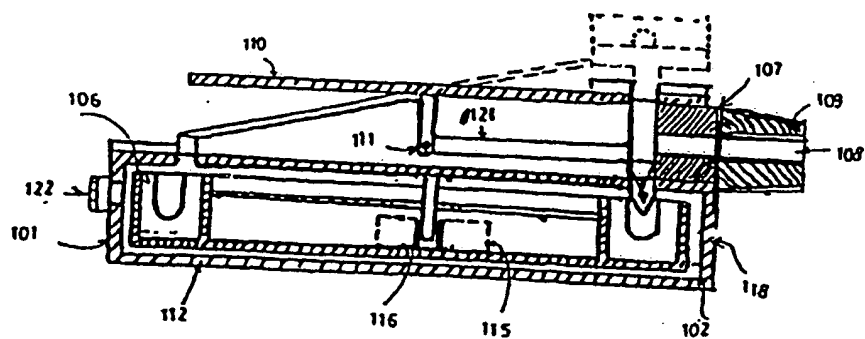


Fig 4

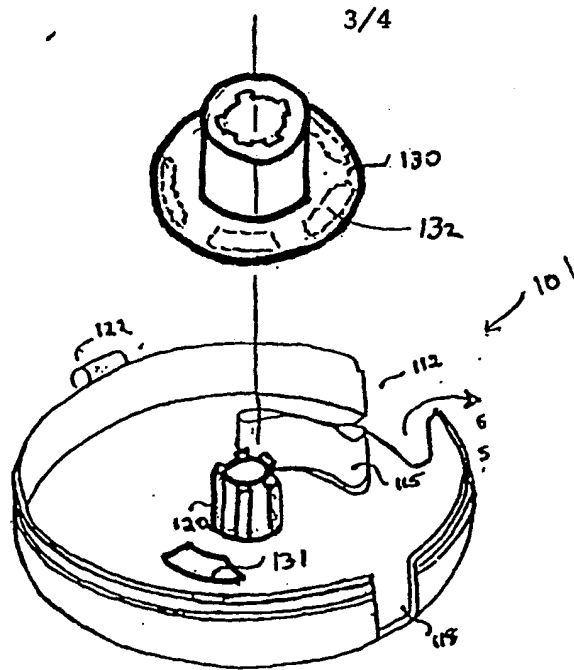


Fig. 5

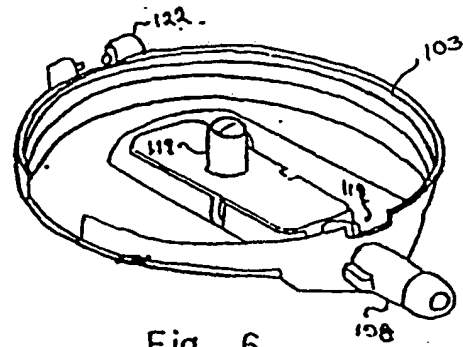


Fig 6

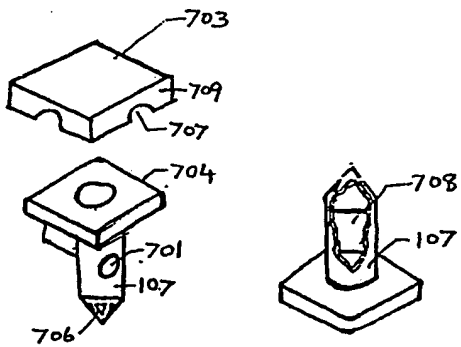


Fig. 7

4/4

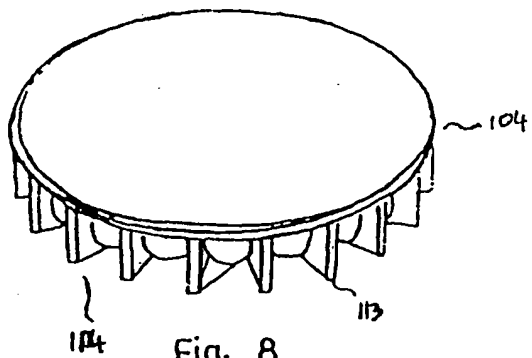


Fig. 8

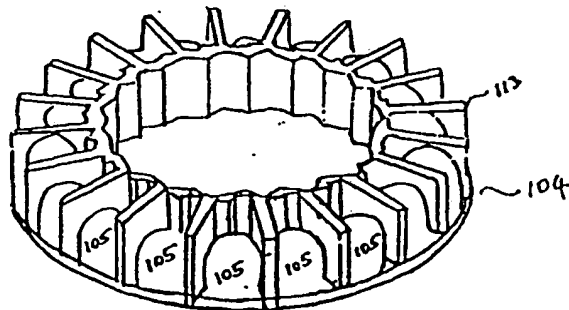


Fig. 9

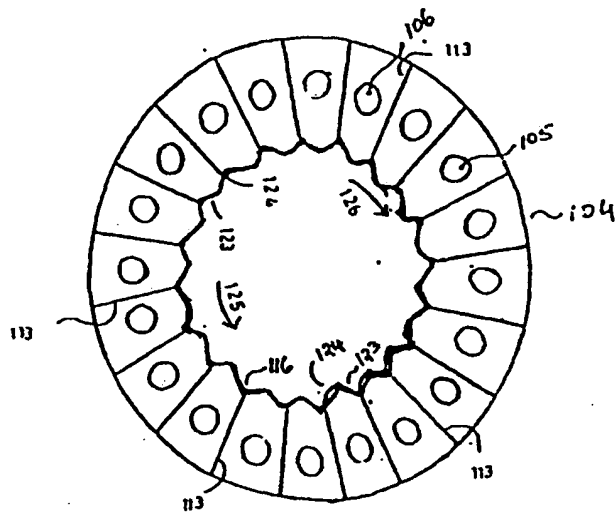


Fig. 10